

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.,
Petitioner

v.

BOEHRINGER INGELHEIM INTERNATIONAL GMBH,
Patent Owner

U.S. Patent No. 8,853,156 to Dugi *et al.*

Issue Date: October 7, 2014

Title: Treatment for Diabetes Patients Inappropriate for Metformin Therapy

Inter Partes Review No.: IPR2016-01565

DECLARATION OF MAYER B. DAVIDSON, M.D.

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I. Introduction

1. I am over the age of eighteen (18) and otherwise competent to make this Declaration.

2. I have been retained as an expert witness on behalf of Mylan Pharmaceuticals Inc. (“Mylan”) for the above captioned *inter partes* review (“IPR”). I am being compensated for my time in connection with this IPR at my standard consulting rate, which is \$500 per hour for non-testifying work. My compensation is in no way dependent on the outcome of this IPR.

3. I understand that the petition for *inter partes* review involves U.S. Patent No. 8,853,156 (the “156 patent”), Ex. 1001. I have considered references published prior to August 6, 2008. I have been informed that such references are referred to as “prior art.” I can confirm that the opinions expressed herein comport with my own understandings based on an independent review of the prior art cited herein.

II. List of Documents Considered

4. In formulating my opinion, I have considered all documents cited in this Declaration and all documents cited in the Petition for *Inter Partes* Review of U.S. Patent No. 8,853,156. I refer to the prior art references and other documents cited in my Declaration using the same terminology as defined and presented in the Petition.

III. My Background and Qualifications

5. I am an expert in the field of medicine, specifically diagnosing and treating type II diabetes mellitus,¹ and I have been an expert in this field since well before 2008. Throughout the remainder of this Declaration, I will refer to the field of diagnosing and treating type II diabetes as the relevant field or the relevant art. In formulating my opinions, I have relied upon my training, knowledge, and experience in the relevant art. A copy of my current curriculum vitae is provided as Ex. 1008, and it provides a comprehensive and current description of my academic and employment history.

6. I received a M.D. from Harvard Medical School in 1961. I took 2 years of my residency at Cornell Medical School, Bellevue Hospital in Internal Medicine from 1961 to 1963. I then completed my residency at the University of Washington in Seattle in 1964 following which I completed a research fellowship at the University of Washington King County Hospital in Endocrinology and Metabolism in 1966.

7. I am currently a Professor of Medicine at both the David Geffen School of Medicine at UCLA and Charles Drew University. I am board certified in Internal Medicine and also board certified in the subspecialty of Diabetes,

¹ I refer to “type II diabetes mellitus” as “type II diabetes.”

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